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EXAMINER

BROWN, JENNINE M

ART UNIT PAPER NUMBER

1755

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,399

Applicant(s)

WASHIZU ET AL.

Examiner

Jennine M. Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims Analysis

For purposes of furthering prosecution and clarifying the record, the examiner is interpreting the terms used in the instant application and claims as having the following meaning:

1. "specific molecule" is interpreted as a "particle".
2. Anything that binds to the particle either temporarily or permanently is interpreted as a "ligand".
3. Anything which causes the particle or the ligand or any combination or subcombination to produce a detectible signal will be considered a "label".
4. Anything that detects the label to be a "detection method".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 15-17, 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Parton, et al. (US 5993631).

Parton, et al. disclose a method of separating a first population of particles from a second population of particles where first population is bound to a ligand and a label which changes the properties of the first population of particles and the second is unbound affecting a separation between the first and second population in a dielectrophoretic field (col. 2, l. 46-58).

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The population of particles disclosed are mammalian cells, plant cells, yeast cells, chromosomes undergoing meiosis or mitosis, oocytes, other chromosomes, bacterial cells, viruses, DNA, RNA and proteins (aka "sample derived from a living body" - col. 3, l. 6-12). The ligands disclosed which bind to the particle can be an antibody, antigen, nucleic acid probe, nucleic acid analog, avidin or avidin like substance (col. 3, l. 31-37; Figures 8-12). Labels disclosed can be magnetic, fluorescent markers, chromophores, enzyme molecules or anything that will produce a detectible signal (col. 4, l. 36-60; Figures 9-12). It is disclosed that the separation between the microelectrodes is 30 μm to 80 μm which are 5 to 20 times larger than the size of the particles (col. 6, l. 52-57). At least one detection method is disclosed for detecting the separated particles (col. 7, l. 29-40; col. 8, l. 29-41; Figure 7). The dielectrophoretic force disclosed is based on the movement of the particle and is related to the frequency of the rotating field from 10 to 10^{10} Hz (col. 11, l. 9-13; col. 12, l. 38 – col. 13, l. 23; Figures 14-16). The electrodes disclosed are capable of horizontal and vertical non uniform fields (Figures 1-6).

Claims 1-10, 14-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Seul, et al. (US 638707 B1).

Seul, et al. disclose a method of separating a first population of particles from a second population of particles where first population is bound to a ligand and a label which changes the properties of the first population of particles and the second is unbound affecting a separation between the first and second population in a dielectrophoretic field. (col. 2, l. 34-37; col. 18, l. 65 – col. 22, l. 22) The population of particles disclosed are lipid vessicles, whole chromosomes, cells, DNA and proteins (aka "sample derived from a living body" - col. 2, l. 39-47). Seul, et al. illustrate both separation and detection techniques for multiple species in the schematics of Figures 8, 9a, 10, 22, 23, 26 and 27. Labels disclosed as enzyme molecules or

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anything that will produce a detectible signal (col. 26, l. 30 – col. 27, l. 34) and quantitative detection is disclosed (col. 35, l. 1 – col. 38, l. 35). Specific examples of immunophenotyping (col. 39, l. 40-56), multiplexed affinity detection (col. 39, l. 60 – col. 40, l. 5) and cellular based functional assays (col. 40, l. 25-54).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Becker, et al. (US 6294063).

Becker, et al. teach an equivalence between movement of sample ("packets") by electrophoretic forces and dielectrophoretic forces (Figure 2; col. 3, l. 42-46; col. 7, l. 63 – col. 8, l. 5; col. 8, l. 31-35). Becker, et al. also teach a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field then detection to give qualitative measurement of the separated specific molecule where the application deals with separation of proteins, nucleic acids and cells (Figures 1, 9B, 12; col. 2, l. 59-63; col. 3, l. 17-23; col. 4, l. 6-10; col. 5, l. 66 – col. 7, l. 4; col. 14, l. 46 – col. 15, l. 7; col. 28, l. 28 – col. 30, l. 44).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-21 and 27-28 of copending Patent Application Publication US 2001/0047941 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the separation method claimed uses a dielectrophoretic force generated by application of voltage by electrodes and influence a "complex of 'a substance binding to a substance to be measured', 'a substance subjected to influence by a negative dielectrophoretic force', and the substance to be measured which binds to said 'substance binding to a substance to be measured'." as well as a detection method which detects these substances to be measured and overlaps the scope of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

1. Becker, et al. teach dielectrophoretic fields in Figure 2 (DEP is used with a force arrow indicating the electrical field force on a polarized packet or bead) and states specifically in column 8, "Dielectrophoretic forces may arise when a packet is placed in an inhomogeneous electrical field (AC or DC)." Furthermore, Becker, et al. teach the equivalence of electrophoretic and dielectrophoretic fields, "Forces F1 or F2 may include many different types of forces. For instance, forces F1 and F2 may be dielectrophoretic, electrophoretic, optical, ... mechanical ...or any other suitable type of force (or combination thereof)." Applicants admit to the equivalence of electrophoretic forces and dielectrophoretic forces in their own specification, (page 14, lines 11-15) "This phenomenon in which neutral molecules move under a nonuniform electric field is called dielectrophoresis (DEP), and the force received by molecules during that time is

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called dielectrophoretic force. If molecules are charged ones, the moving mode is such one as comprising electrophoretic forces in addition to dielectric forces." Regarding the parameters in dielectrophoretic forces, again Applicants specification does not state that the electrode shape is a parameter, only the permittivity and conductivity which are the material that the electrode is made of are important as stated (page 26, lines 10-14), "It can be understood from the above mentioned general equation of dielectrophoretic forces that parameters involved in dielectrophoretic forces of substances receiving dielectrophoretic forces are, in general, permittivity and conductivity of the substances and the medium, the size of the substances, and the frequency of the applied electric field." The field used is also stated such that it is inherent to the controller of the electric field and not the electrodes in Applicants specification (page 27, lines 22-24), "In the present invention, the electric field to be applied can be any of an AC electric fields and a DC electric field, and is generally preferable to use the AC electric field." Becker, et al. teach the same in column 4, "The addressing of electrode elements with electrical signals may initiate different field distributions and generate dielectrophoretic manipulation forces that trap, repel, transport, or perform other manipulations upon packets on and above the electrode plane. By programmably addressing electrode elements within the array with electrical signals, electric field distributions and manipulation packets may be manipulated along arbitrarily chosen or predetermined paths." The definition of non uniform field then needs to be determined to see where Applicants arguments are being determined by the specification. The only references to the non uniform field are in the amended specification page 3, lines 9-12, "the field being formed by electrodes which have a structure capable of forming a horizontally and vertically ununiform electric field" where Applicants alledge the electrode structure is what gives the field its "nonuniformity". It has been held that the recitation that an element is

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"capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Regarding the definition of "packet" and its equivalence, page 2 of Becker, et al. states "As used herein, 'packet' refers to compartmentalized matter and may refer to a fluid packet, an encapsulated packet, and/or a solid packet. A fluid packet refers to one or more packets of liquids and gases ... A fluid packet may refer to a droplet of water, a droplet of reagent, a droplet of solvent, a droplet of solution, a droplet of a sample, a particle or cell suspension, a droplet of an intermediate product, a droplet of a final reaction product or a droplet of any material ... An encapsulated packet refers to a packet enclosed by a layer of material. An encapsulated packet may refer to vesicle or other microcapsule of liquid or gas that may contain reagent, sample, a particle, a cell, an intermediate product, a final reaction product, or any material. The surface of an encapsulated packet may be coated with a reagent, a sample, a particle or a cell, an intermediate product, a final reaction product or any material ... A solid packet refers to a solid material that may contain, or be covered with a reagent, a sample, a particle or cell, an intermediate product, a final reaction product, or any material. An example of a solid packet is a latex microsphere with reagent bound to its surface suspended in an aqueous solution." Examiner maintains the previous 102(e) rejection under Becker, et al.

2. New rejections have been made after searching for newly added claims 24-25.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5277774 A relates to the state of the art in 1994 where electrical fields manipulate solutions in both horizontal and vertical axes for electrophoretic separation.

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US 5569367 A relates to the state of the art in 1996 where spatially non-uniform fields generated at electrodes use pulsed frequencies of 10 Hz to 10 MHz or more.


US 5626734 A relates to the state of the art in 1997 where dielectrophoresis is used as a method of separating living and dead animal cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (571) 272-1364. The examiner can normally be reached on M-F 8:00 AM - 6:00 PM; first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (571) 272-1362. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jmb


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